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November 12, 2024

Via ECF

Honorable Renée Marie Bumb
United States District Court
for the District of New Jersey
U.S. Courthouse, 4th & Cooper Streets
Camden, NJ 0810

Re: *In re Valsartan, Losartan, & Irbesartan Products Liability Litigation*, No. 1:19-md-02875 (D.N.J.)

Dear Chief Judge Bumb:

Plaintiffs respectfully submit this letter in response to Defendants' October 29, 2024 letter (ECF 2916). Plaintiffs also attach herewith as **Exhibit A** the Third Circuit's precedential decision issued last week in *Huertas v. Bayer US LLC*, No. 23-2178 (3d Cir. Nov. 7, 2024), and discuss the import of same in Part II below.

I. Introduction

Defendants seek a complete redo of this entire litigation for all intents and purposes, upending six years' worth of concentrated work and established law of the

case. Defendants unabashedly ask this Court to reconsider nearly all major prior rulings in this litigation, including well-reasoned opinions rejecting the motions to dismiss, granting class certification, denying decertification, and granting partial summary judgment to TPP Plaintiffs, and finding in favor of general causation. Those prior rulings were the culmination of years of protracted fact and expert discovery, over a hundred depositions taken, scores of briefs and legal opinions written spanning thousands of pages, and countless hours spent by the parties and three different jurists (Judges Kugler, Schneider, and Vanaskie). To reconsider this vast law of the case under which the parties have been laboring for years would be enormously inefficient, overwhelmingly prejudicial to Plaintiffs and the countless consumer and TPP class members (to whom class notice has been disseminated at a cost of nearly a million dollars), and the many personal injury plaintiffs suffering with or who have already passed away from cancer.

Defendants tried this exact gambit before, when the litigation was reassigned following Judge Kugler's retirement. *See* ECF 2770 (status report in which Defendants suggested the very same do-overs they re-raise now). This Court rightly observed then that Defendants' suggestions to start from scratch in this litigation "are simply not helpful." ECF 2771. This assessment was correct. Judicial reassignment is not license to request broad reconsideration of prior rulings that

Defendants do not like. "[C]ourts should be loathe" to depart from prior decisions.[1] Indeed, "to maintain consistency and avoid judicial reconsideration of matters once decided during the course of a single continuing litigation,"[2] the "law of the case doctrine directs courts from re-deciding issues that were resolved earlier in the litigation."[3] Courts in this District and others will not re-decide the law of the case absent "extraordinary circumstances,"[4] such as a change in intervening law or new evidence,[5] none of which we have here.

For instance, in a procedurally similar case, *In re Sulfuric Acid Litigation*, 847 F. Supp. 2d 1079 (N.D. Ill. 2011), the defendants sought to decertify a class after the originally-assigned judge retired. Those defendants argued changed circumstances warranted revisiting the predecessor judge's certification and summary judgment

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[1] *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988); *Fagan v. City of Vineland*, 22 F.3d 1283, 1290 (3d Cir. 1994) ("a successor judge should not lightly overturn decisions of his predecessors in a given case"); *Hayman Cash Reg. Co. v. Sarokin*, 669 F.2d 162, 165 (3d Cir. 1982) (if the law of the case doctrine applied, "Judge Sarokin should have deferred to Judge Richey's [prior] decision").
[2] *Pub. Interest Res. Grp. of N.J. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 116 (3d Cir. 1997).
[3] *In re Pharmacy Benefit Managers Antitrust Litig.*, 582 F.3d 432, 439 (3d Cir. 2009).
[4] *In re Plavix Marketing, Sales, Practices & Prods. Liab. Litig.* (*No. II)*, 123 F. Supp. 3d 584, (D.N.J. 2015) (Wolfson, J.) (refusing to revisit predecessor judge's rulings absent "extraordinary circumstances").
[5] *In re Celgene Corp., Inc. Sec. Litig.*, No. 18-cv-4772, 2024 WL 4047674, at *8 n.19 (D.N.J. Sept. 4, 2024) (Farbiarz, J.)

decisions. The successor judge refused to do so, noting that the twin goals of the law of the case – judicial economy and unfair prejudice – did not warrant reconsideration, especially because the case was so procedurally advanced. *Id.* at 1082. Judge Wolfson reached a similar conclusion in the Plavix MDL, in which she refused to revisit the prior ruling of a transferee judge on a motion to dismiss issued prior the creation of the MDL, which centralized all cases under her. *In re Plavix*, 123 F. Supp. 3d at 614; *see also, e.g.*, *Jermyn v. Best Buy Stores*, 276 F.R.D. 167, 169 (S.D.N.Y. 2011) (collecting cases) (refusing to revisit earlier class certification decision).

Defendants' suggestion that this Court revisit the prior rulings at previous major inflection points of this litigation (motion to dismiss, class certification, summary judgment), in the complete absence of extraordinary circumstances, would be the epitome of inefficiency and unfairness. Instead, as discussed below, there are much more appropriate, efficient, and just ways to proceed.

II. The Third Circuit's *Huertas* Decision Adopts the Eleventh Circuit's Approach in *Debernardis* and Validates Plaintiffs' Economic Worthlessness Theory

On November 7, 2024, the Third Circuit issued a precedential decision in *Huertas v. Bayer US LLC*, No. 23-2178 (3d Cir. Nov. 7, 2024) (Ex. A hereto). The Third Circuit confirmed the validity of economic worthlessness theories of damages

for already-consumed, contaminated health products that may have otherwise still provided some health benefit (i.e., were not placebos). This decision rebuffs Defendants' attempt to undo years' worth of work and law of the case in this litigation.

The plaintiffs in *Huertas* sought to recover the full amounts paid for *already-consumed* antifungal sprays that were recalled in 2021 after Bayer discovered benzene contamination dating back to lots manufactured as early as 2018; benzene is a carcinogen that is not an ingredient of any properly manufactured healthcare product, but was present due to manufacturing defects. *Id.* at *4-5. Neither the defendant nor the plaintiffs knew of the contamination at the time of sale. *Id.* And there was no allegation that the products were not effective, as the Court observed that lack of value could be asserted even in the absence of a claim that the defect impacted the efficacy of the products. *Id.* at *14-15.

The district court dismissed the complaint with prejudice, finding that the plaintiffs lacked Article III standing to pursue their worthlessness theory. *See Huertas v. Bayer U.S., LLC*, No. 2:21-cv-20021, 2023 WL 3773139 (D.N.J. May 23, 2023) (Wigenton, J.). The Third Circuit reversed, holding among other things as follows:

> One way "a plaintiff might successfully plead an economic injury [is] by alleging that she bargained for a product worth a given value but

received a product worth less than that value." *J&J*, 903 F.3d at 283. This is known as the benefit-of-the-bargain theory of injury. Under this theory, "[t]he economic injury is calculated as the difference in value between what was bargained for and what was received." *Id.* **Plaintiffs here rely on the benefit-of-the-bargain theory to establish injury-in-fact, arguing that they paid full purchase price for products "free of contaminants and dangerous substances," App. 255, but received products that were defectively manufactured with "harmful levels of benzene," causing them to be "adulterated" and therefore "worthless," App. 254. We conclude that Plaintiffs can rely on this theory of economic injury.**

…

Our conclusion that contaminated products are worth less than uncontaminated products is consistent with decisions from other Courts of Appeals. For example, in *In re Aqua Dots Products Liab. Litig.*, several parents sued a manufacturer that produced a toy with defective components that, when ingested, metabolized into a chemical substance that can cause a variety of side effects and could even lead to death. 654 F.3d 748, 749 (7th Cir. 2011). The parents' children were not harmed by the toy, but the Seventh Circuit nonetheless concluded that the parents had standing to sue under a benefit-of-the-bargain theory because "they paid more for the toys than they would have, had they known of the risks the beads posed to children." *Id.* at 751. **Similarly, in *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076 (11th Cir. 2019), the Eleventh Circuit held that plaintiffs who purchased adulterated dietary supplements under the FDCA "received … defective product[s] that had no value." Id. at 1085. The Eleventh Circuit explained that its "conclusion [was] consistent with the well-established benefit-of-the-bargain theory of contract damages, which recognizes that some defects so fundamentally affect the intended use of a product as to render it valueless." *Id.***

…

> Given that contaminated products are unfit for their intended use, they are inherently worth less than the uncontaminated products Plaintiffs thought they were purchasing.

Huertas, at *9, *15-16 (Ex. A) (emphasis added).

Huertas is on all-fours with this litigation in nearly every important factual and legal respect. Both cases involve express and implied warranty claims, common law fraud claims, and consumer protection law claims asserted for purchases of a healthcare product that was contaminated with a carcinogen that should not have been present at the time of sale. The products in both cases were consumed or used, and there was no claim in *Huertas* that the product failed to provide efficacy or was a placebo. Both products were eventually the subject of recalls based on the later-discovered contamination that occurred long after the product was used. Both sets of plaintiffs allege the contaminated products (including those consumed long ago) were *adulterated and therefore economically worthless at the point of sale* due to the presence of an unbargained-for contaminant that "'so fundamentally affect[s] the intended use of a product as to render it valueless'" regardless of whether the product nevertheless afforded some quantum of residual benefit. *Huertas*, No. 23-2718, at *16 (quoting *Cottrell v. Alcon, Lab'ys*, 874 F.3d 154, 1085 (3d Cir. 2017)); *accord FTC v. Figgie Int'l, Inc.,* 994 F.2d 595, 606 (9th Cir. 1993) (consumers entitled to "full refund" for heat detectors sold based on false representations, but which still

functioned: "**To understand why [a full refund is appropriate even when the product maintains a modicum of value], we return to the hypothetical of the dishonest rhinestone merchant. Customers who purchased rhinestones sold as diamonds should have the opportunity to get all of their money back. The seller's misrepresentations tainted the customer's purchasing decisions**.") (emphasis added); *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 524 (6th Cir. 2015) (approving zero value damages model where probiotic nutritional supplement did not work as advertised and holding that "whether purchasers were nevertheless satisfied with [the product] does not affect the propriety of a full-refund damages model"); *In re Recalled Abbott Infant Formula Prod. Liab. Litig.*, 97 F.4th 525, 530 (7th Cir. 2024) ("A universal defect inherent in a product—such as a design defect or a fundamental flaw—renders each product valueless to each plaintiff, as in *Aqua Dots* and similar cases.").

Simply put, the Third Circuit has now made clear in no uncertain terms that under the factual and legal circumstances extant both in *Huertas* and this litigation, and involving warranty, fraud, and consumer protection law claims asserted relating to a carcinogen-contaminated healthcare product previously sold and ingested (with perhaps some residual health benefit), economic worthlessness damages are available as a matter of law because the defect at issue is fundamental. *Huertas*, at

*16 (citing and adopting *Debernardis*). Defendants' suggestion to the contrary (*see, e.g.*, ECF 2916 at 4) is inconsistent with existing and now indisputably precedential Third Circuit law.

III. It Would Be Significantly Prejudicial and Manifestly Unjust to Scuttle the Economic Loss Class Cases As Defendants Propose

Huertas aside, the centerpiece of Defendants' request to undo years' worth of litigation on the class side of this case is their grasping onto the Court's apparent concern with TPP Class Plaintiffs' worthlessness theory going to a jury on the record as-is without any perceived guidance or guardrails. Apart from Judge Kugler's well-reasoned opinions on motions to dismiss, class certification, and summary judgment, Plaintiffs submitted to this Court fulsome briefing on whether Plaintiffs may pursue a worthlessness theory under a breach of express warranty claim (the Court has confirmed that this issue is not of concern with the consumer protection law and common law fraud claims). *See* ECF 2844 & Appendix thereto, ECF 2869 & Appendix thereto.[6] The case law unambiguously supports that Plaintiffs may pursue full value (i.e., 100% of the purchase price paid) under a breach of warranty claim (and can recover the full amounts paid pursuant to Plaintiffs' other theories, including fraud and violation of consumer protection statutes). This is especially so

[6] Interestingly, in that round of briefing, Defendants even contradicted their own prior authority. *See* ECF 2869 at 3-4 (cataloguing same).

when a "fundamental defect" or a failure of the defendant to provide the "essence of the bargain" exists, as recognized in the numerous authorities submitted by Plaintiffs in the prior briefing, as well as in the Third Circuit's *Huertas* decision. And importantly, while a finding of adulteration is legally dispositive as to economic worthlessness,[7] *Huertas* held that this is not the only way for a jury to arrive at such a conclusion:

> We recognize, as Bayer points out, that *Debernardis* is distinguishable to the extent that it concluded that adulterated supplements were worthless based on the FDCA's explicit prohibition on "the sale of adulterated dietary supplements," which was in turn based on Congress's judgment that "such substances could not safely be ingested." 942 F.3d at 1085. Bayer, however, cites no authority suggesting that a legal prohibition is the sole basis upon which our conclusion here can be reached. Indeed, whether through a legal prohibition or a product recall, the end result is the same: if their products are contaminated, they are unusable. Although Bayer's recall notice explained "the levels detected are not expected to cause adverse health consequences," App. 136, the economic injury addressed here is not for costs associated with adverse health consequences.

Ex. A at *16 n.14.

[7] Aside from being economically worthless as a matter of law under *Huertas*, Dr. Conti's numerous expert opinions in this litigation provide the economic underpinning for such a conclusion, consistent with economic literature. *See, e.g.*, P.M. Danzon and E.L. Keuffel, "Regulation of the Pharmaceutical-Biotechnology Industry," Economic Regulation and Its Reform: What Have We Learned?, ed. N.L. Rose, University of Chicago Press: Chicago, IL, 2005, pp. 407-84 (noting patients and third-party payors cannot test or evaluate for themselves safety and quality of prescription drugs, and therefore must rely on FDCA-imposed obligations on manufacturers to sell appropriate products).

However characterized, this is the situation here. Defendants' valsartan-containing drugs ("VCDs") indisputably contained high levels of extremely potent human carcinogens NDMA and/or NDEA that admittedly[8] made them "unfit for their intended use[,]" *Huertas*, at *16. The products were deemed "adulterated" by the FDA and therefore "were worthless based on the FDCA's explicit prohibition" of their sale (21 U.S.C. § 331) as a matter of law "based on Congress's judgment[,]" *Huertas*, at *16 & n.14, and separately, which a reasonable jury could quite obviously determine to be a fundamental defect that goes to the very essence of the expected-but-unfulfilled bargain (namely, an FDA-approved generic version of valsartan that met **all** the criteria – safety, quality, purity, identity, strength, cGMP compliance – so as to be able to be sold lawfully in this country).[9] This is particularly

[8] For instance, ZHP, Teva, and Torrent recalled *all* of their VCDS within expiry, and ZHP issued a recall statement acknowledging that its VCDs and those made with its API amounted to an "unacceptable carcinogenic risk."

[9] Notably, Plaintiffs' prior briefing to the Court (ECF 2844, ECF 2869) contains many authorities supporting Plaintiffs being allowed to pursue a worthless damages theory *even if* Defendants' VCDs provided some residual clinical benefit (e.g., they were 'effective' at controlling blood pressure). *Huertas* is yet another instance of such an authority. Defendants, by contrast, cite no on point cases in support of their position that residual benefits for a fundamentally defective and/or legally-prohibited-from-sale product legally forecloses a full reimbursement damages model. *Huertas* forcefully rejected this argument. *See generally* ECF 2844 & Appendix thereto, ECF 2869 & Appendix thereto.

so when at all times there were uncontaminated, safe and effective valsartan products available to consumers (and myriad other medicines and treatments).

This is not an eleventh-hour theory. Plaintiffs have been litigating this case in accordance with the law of this case, which judicially recognized the viability of this theory, for years. Judge Kugler held in no uncertain terms that Plaintiffs may pursue a worthlessness theory based on the VCDs' adulteration and fundamentally defective nature of the pills due to the contamination *even if* Defendants' VCDs might have had some residual value, such as controlling blood pressure:

> ***This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure.*** Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for.

ECF 775 at 20 (emphasis added). The parties have labored under, and Plaintiffs have relied on, this holding by Judge Kugler for years. *See also, e.g.*, ECF 728 at 13 ("Under this theory, Plaintiffs seek reimbursement for the full amount paid for the VCDs, that is, their out-of-pocket expenditures. This is not some amorphous allegation of an economic loss lacking a concrete way of calculating it. This allegation suffices for a factfinder to value Plaintiffs' purported economic injury.").

Huertas resolves that Plaintiffs are permitted to argue Defendants' VCDs are economically worthless. *Huertas*, at *15-16 & n.14. In the event the jury somehow finds the Defendants' VCDs contaminated with NDMA and/or NDEA (which is undisputed) but not adulterated, then the jury may still find Defendants' VCDs to have been worthless (i.e., zero value) because of the fundamental nature of the defect. *Huertas*, at *16 & n.14 ("Indeed, whether through a legal prohibition or a product recall, the end result is the same: if their products are contaminated, they are unusable."); *see also id.* ("Given that contaminated products are unfit for their intended use, they are inherently worth less than the uncontaminated products Plaintiffs thought they were purchasing.").

For years after the motion to dismiss rulings, the Court repeatedly reaffirmed Plaintiffs' economic worthlessness theory. Also, the economics and healthcare policy expertise that grounded Dr. Conti's economic worthlessness opinion and economics and health policy methodology that is grounded in her expert discipline of healthcare economics, and Plaintiffs' ability to put both in front of a jury to support a worthlessness theory "even if [VCDs were] medically efficacious for their

purpose" *id*., again,[10] and again,[11] and again,[12] including up through when the TPP trial was supposed to commence the first time in March 2024. This is the law of the case:

> "Ds have repeatedly sought the Court to repudiate Ps worthlessness theory: at the motion to dismiss stage, at the class certification stage, and recently in a motion to decertify the certified classes... ***Regardless of what this argument is called...these theories hinge on different legal perspectives and on genuinely disputed, material facts for the trial fact-finder.*** Pursuant to Rule 56(a), the parties' arguments dispute a material fact about the amount of damages—from none to the full amount TPPs reimbursed for the insureds' scripts."

ECF 2694 at 57 (emphasis added); *see also id.* at 20 & n.17 ("[T]he Court has expressly stated Ps worthlessness theory raises a genuine issue of material fact and

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[10] ECF 728 at 11 ("Plaintiffs' alleged economic injury is that they did not receive the benefit of their bargain when they purchased Defendants' VCDs because they were contrary to Defendants' warranties and representations—that is, the VCDs were adulterated, misbranded, non cGMP compliant, unlawful to sell, and therefore essentially worthless").

[11] ECF 2261 at 88 ("The Court has considered carefully all of the parties' arguments and concludes that Dr. Conti has set forth a general calculus, i.e. mathematical model, which, although possibly flawed because the data are not available or forthcoming, ***may reliably support her presumption of the worthlessness of the sold VCDs.***") (emphasis added).

[12] ECF 2657 at 7 ("The *Comcast* situation is exactly what the parties do NOT have here. Plaintiffs here have ONE model of damages that depends on Conti's worthlessness theory."); *see also* ECF 2469 at 13 (Special Master stating: "Plaintiffs point out that the Court has already determined that the VCDs contaminated with carcinogenic substances are economically worthless, 'regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure.'").

leaves that for the fact-finder."). In sum, the law of this case has repeatedly reaffirmed the validity of Plaintiffs' worthlessness theory as a matter of law, and found sufficient Plaintiffs' evidence supporting it, both fact and expert. *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 459, (2016) ("Once a district court finds evidence to be admissible, its persuasiveness is, in general, a matter for the jury.").

Moreover, Plaintiffs' theory aside, the Court already has indicated it likely will allow Dr. Conti to presume Defendants' VCDs were worthless and to testify on the estimated damages for the subclass. This is most consistent with *Huertas*, where the Third Circuit adopted *Debernardis* and found that if the jury determines that Defendants' products are adulterated, that legal prohibition renders the products economically worthless as a matter of law. *Huertas*, at *15-16 & n.14. In such case, the Court should instruct the jury to simply compute the full value damages based on the evidence regarding computation of damages. So even if this Court finds that Dr. Conti should not be allowed to testify that in her own opinion the VCDs are worthless, she may properly rely on the assumption that the VCDs were adulterated and legally prohibited from sale or contained a fundamental defect (and therefore, worthless) as she did in her expert reports (*see, e.g.*, ¶ 5 of Dr. Conti's original report and primary TPP subclass trial merits report).

In the event the jury finds Defendants VCDs to have been adulterated for some or all of class period, and therefore subject to a legal prohibition on their sale, Defendants are legally foreclosed from asserting value per *Huertas*. However, adulteration aside, if the case proceeds on a fundamental defect-based theory, and Defendants are permitted (as the Court has indicated they will be) to argue to a jury that their contaminated VCDs had "some" value, such that a jury should not award 100% of the purchase price paid, the Court may determine that this will be permitted, and the jury may accept or reject Defendants' proposition.[13] Plaintiffs' arguing worthlessness to the jury, while also acknowledging Defendants' mitigation/offset defense under certain circumstances is something the jury may consider to reduce damages below 100%. This is *not* the same as Plaintiffs' affirmatively arguing themselves a worth-some-amount-less theory.[14] In either case, the jury should be

[13] What Defendants really want to do is prevent Plaintiffs from ever stating to the jury at trial that the latter may award less than 100% of the price paid for VCDs. Defendants' gambit fails. Plaintiffs will argue to the jury that the VCDs were worthless. Defendants, in turn, will argue their mitigation/offset defense that damages should not be 100% because class members received some value (that was not entirely outweighed by a fundamental defect). A jury can credit Plaintiffs' worthlessness theory while also crediting in part Defendants' mitigation/offset defense, to arrive at a less than 100% damages award. Juries do this all the time.

[14] And again, Plaintiffs did not need to develop that affirmative theory themselves because the years-long law of this case repeatedly reaffirmed that Plaintiffs may present a worthlessness theory to a jury even if the VCDs might have had some quantum of residual value, and a jury can award damages between 0% and 100% of the amounts paid. Judge Kugler's dicta at the motion to dismiss stage about whether

permitted to decide the factual question of the economic damages suffered by Plaintiffs. The law of the case indeed found as much. Judge Kugler repeatedly found Plaintiffs' worthlessness theory fit as a matter of law to go to the jury regardless of evidence of medical efficacy (e.g., ECF 775 at 20), and yet left the decision as to value to the factfinder, more or less explicitly recognizing the mitigation/offset nature of Defendants' argument. Regardless, the law of this case for years – up until last month, just two weeks before the TPP Subclass Trial was set to begin a second time – was whether damages are 100% of the prices paid, or some lesser amount, is for a jury to decide, not a court. This was the entire point, years ago, for the selection

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Plaintiffs had standing based on a "worth less" theory is a non-sequitur because standing is not a fact-based determination, and once a party has standing they may remain in court (as was the case here), regardless of what legal theory of damages they pursue, which is a different question. Regardless, Defendants are wrong that damages are an all or nothing proposition for the jury, and that amending the complaints would somehow wreak havoc on this litigation they themselves seek to completely upend; it would merely conform the pleadings to the evidence. Indeed, Defendants already developed their theory during discovery that their nitrosamine-laced pills had some value. They can present that argument to the jury per the Court's findings, and the jury will decide.

of a TPP subclass trial in the first place,[15] which Plaintiffs relied on in undertaking years of preparation and expense.[16]

A word on *Zantac*. At the October 22, 2024 Conference, the Court posited whether Judge Rosenberg's *Zantac* decision might be instructive here. It is not. For one, the Eleventh Circuit has already reversed Judge Rosenberg once on whether TPPs have standing to assert claims for overpaying for allegedly worthless drugs. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, No. 21-10335, 2022 WL 16729170, at *1 (11th Cir. Nov. 7, 2022). And *Huertas* adopted the Eleventh Circuit's reasoning in *Debernardis*, which in turn was the guiding authority for the later Eleventh Circuit *Zantac* opinion. The remainder of that litigation remains on appeal (including the

[15] *See* July 28, 2022 CMC Tr. at 23 ("But I still think the question we need to have answered or seem to need to have answered is whether or not this stuff was contaminated and whether it was worth anything, you know, to the purchasers or anyone else who paid for it. And I think the easiest way, the fastest way to get there is a TPP single plaintiff case, to be honest with you. I continue to believe that."). The Court's focus for both sides has been on determining the worth or value if any of the VCDs rather than the terminology used to describe it.

[16] Indeed, at first, Plaintiffs prepared for an individual TPP trial at Judge Kugler's direction. After certification, Plaintiffs were directed by Judge Kugler to prepare for a TPP subclass trial. While the focus always remained on TPP claims, the shift from an individual to a class trial meant Plaintiffs undertook the time and expense of tendering four separate damages reports by Dr. Conti. She was deposed after each over a total of five days. And her opinions – the exact same opinions she was to proffer at the adjourned October TPP subclass trial – were explicitly found to be reliable and admissible at the class certification stage. *See* ECF 2261 at 88.

premature dismissal of the class claims based on procedurally improper inferences as to the merits).

Factually, *Zantac* is distinguishable from this litigation for myriad reasons. Most notably, nitrosamines in Zantac and ranitidine were the alleged result of degradation of the API molecule itself, not a manufacturing process-created contamination as here and in *Huertas*. The significance of this is two-fold: (1) whether nitrosamines were present in a particular Zantac or ranitidine product might vary based on degradation conditions including time and temperature of storage and delivery, whereas here, it is undisputed that every single VCD coming off the production line contained quantified nitrosamines – based on Defendants' own testing, root cause analyses, and statements to the FDA and the public; and (2) the nitrosamines in Zantac are inherent with the approved active pharmaceutical ingredient (i.e., ranitidine was approved and the degradation risk is inseparable from the API), which is not true with the unapproved NDMA and NDEA in VCDs that resulted from a modified manufacturing process that differed from the process approved by the FDA for the brand product (indeed, at all material times there were non-contaminated VCDs on the market that did not contain any NDMA or NDEA).

Judge Rosenberg's *dicta* about "worthless" and "worth less" are immaterial to this litigation and implicitly rejected by the Third Circuit. Worthlessness is, by

definition, an amount "worth less" than the amounts paid for Defendants' VCDs, as *Huertas* explicitly recognized. *See also, e.g., Debernardis v. IQ Formulations, LLC,* 942 F.3d 1076, 1085 (11th Cir. 2019) ("This conclusion is consistent with the well-established benefit-of-the-bargain theory of contract damages, which recognizes that some defects so fundamentally affect the intended use of a product as to render it valueless."); *accord In re Zantac*, 2022 WL 16729170, at *1 (in reversing Judge Rosenberg, citing *Debernardis* approvingly on this point).[17] Moreover, as discussed above, the law of the case on which Plaintiffs explicitly relied for years endorsed worthlessness as a viable damages theory *even assuming* the pills controlled blood pressure, and that Dr. Conti's opinions as to same "reliably support her presumption of the worthlessness of the sold VCDs." ECF 2261 at 88.[18]

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[17] As these terms are used in common parlance, "worthless" typically signifies little to no value of something in and of itself, where as "worth less" is typically used to compare the value of one thing to another. The contaminated VCDs could rightly be considered worthless and 'worth less' than the uncontaminated VCDs that were on the market at the same time and as indicated, the *Huertas* and *Debernardis* courts readily reconcile the use of the terms 'worthless', 'worth less' and 'valueless' in the context of a benefit-of-the-bargain inquiry with each being an allowed descriptor to argue the value of the economic injury.

[18] Nevertheless, whether Dr. Conti herself is of the opinion that the VCDs are worthless under the principles of economics and health policy, for the purposes of her report, she assumes liability for the sale of an adulterated product based on counsels' legally supported instruction and her damages calculations based on the IQVIA data and data produced by Defendants can be presented to the jury based on that assumption.

On multiple occasions, Defendants' letter also mischaracterizes Dr. Conti as providing a "retroactive" or hypothetical world opinion of worthlessness. This is not what she does. Her repeatedly stated opinion, as recognized and held in the law of this case, is that the VCDs at the time and point of actual sale were economically worthless because the pills sold *at that time* were adulterated, not made in accordance with cGMP, and contained contaminating nitrosamines, and therefore the value *at that time* was zero. *See* ECF 2694 at 32 (summary judgment opinion stating that whether the drugs were adulterated at the time of sale is "the central fact in dispute in this matter" and leaving that determination for the jury as the fact-finder) (emphasis added). To the extent this Court questioned whether Plaintiffs' theory and Dr. Conti's opinions here were different than those of the plaintiffs and Dr. Conti herself in the *BCBS* case, they were not. There, the plaintiffs also sought full purchase prices paid for seventeen different drugs sold between 2002 and 2005; the FDA did not declare all of the seventeen different drugs adulterated until 2005. *BCBS v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531, 538, 543-44, 554 (E.D. Pa. 2019). In other words, just like the plaintiffs in *BCBS*, Plaintiffs here are not arguing "retroactive" adulteration based on a post-sale FDA determination; rather, as in *BCBS*, the *same deficient conditions* that led the FDA to declare the drugs adulterated once the salient facts became known for valsartan existed for years

earlier at the point of manufacture and sale. And similarly, in *Huertas*, the FDA never formally declared Bayer's benzene-contaminated antifungal sprays adulterated, and yet the Third Circuit expressly permitted the plaintiffs to pursue their claims on the theory that the products were in fact adulterated. *Huertas*, at *9-10, *16 & n.14.

IV. The Path Forward on the Economic Loss Class Cases

The landscape is thus: Plaintiffs reasonably relied on years-long, repeatedly reaffirmed law of this case (including on the eve of the first-scheduled trial in March 2024) that their theory and expert evidence of worthlessness may be presented to a jury. A few weeks before the second-scheduled TPP subclass trial, based on the status of the litigation, this Court did not yet have a comfort level with the idea that a jury might be put in a position to award Plaintiffs the full purchase price for VCDs, when the drugs were purchased years ago and when the drugs were not a placebo (i.e., did nothing, had no efficacy or benefit whatsoever, and would restrict worthlessness damages to the factually implausible situation of a pharmaceutical manufacturer circulating a placebo under the name of an FDA-approved drug). The Third Circuit recently affirmed in *Huertas* the correctness of nearly all of Judge Kugler's prior decisions constituting the law of the case, most prominently the

viability of the worthlessness theory under the circumstances here.[19]

The logical and efficient path forward for the certified economic loss classes is clear: the Court should allow Plaintiffs to supplement the TPP subclass expert record, and to set a schedule for merits expert discovery for a Consumer Subclass Case against ZHP, Teva, and Torrent, for whom Plaintiffs have now twice expended substantial time and financial resources working up the liability case for trial.

Plaintiffs' submission of expert report(s) for the consumer economic loss case focusing on a market assessment and consumer willingness to pay would be further evidence of damages on which a jury may agree with Plaintiffs that the VCDs were worthless, even if the VCDs controlled blood pressure. This would completely allay any hesitation as to the damage component of the since-adjourned TPP subclass trial. And because merits expert reports were not submitted in the consumer subclass cases, this area of expert opinion can be addressed without hesitation; the remaining areas of expert opinion would be very similar to those for the bellwether TPP

[19] One exception is Judge Kugler's finding that the Plaintiffs had not adequately alleged a "worth less" theory. ECF 728 at 13. *Huertas* makes abundantly clear that allegations of contamination are sufficient to establish that a product is worth less. *Id.,* at *16 ("Given that contaminated products are unfit for their intended use, they are inherently worth less than the uncontaminated products Plaintiffs thought they were purchasing."). Plaintiffs would respectfully request leave of the Court in light of this to amend the complaint to more explicitly add a worth less theory, which will not prejudice Defendants.

subclass trial (e.g., cGMP expert opinions, etc.), so the prior rulings in the latter likely could carryover in large part.

Defendants' previewed opposition to this proposal (*see* ECF 2916 at 3-4) lacks merit. First, Defendants put the cart before the horse in arguing that a consumer/market analysis might show a substantial number of consumers would willingly pay some amount less for adulterated, nitrosamine-laced valsartan (even if they were legally able to choose it, and they were not), when other non-adulterated valsartan and other medications and treatments were on the market at the same time. Plaintiffs have not tendered a merits expert report(s) or consumer survey-type analysis yet, so it is entirely premature and improper for Defendants to presuppose what those reports or analyses might show. Defendants' conjecture that any reasonable consumer would willingly choose to purchase nitrosamine-contaminated VCDs over otherwise identical competing VCDs without the nitrosamines and other alternative treatments is exceedingly far-fetched. This is why Defendants' survey expert, Dr. Punam Keller, whose opinion was speculation and not based on any actual survey or other reproducible analysis, was stricken at class certification. *See* ECF 2261 at 77-79.

Second, as noted *supra* Parts I & III, Plaintiffs understandably proceeded in this litigation for years in reliance on the explicit law of this case that repeatedly held

their worthlessness theory and evidence, including Dr. Conti's opinions, can be presented to a jury. Certainly, last month, this Court expressed its hesitation with Plaintiffs' doing so. The issuance of *Huertas* by the Third Circuit should, respectfully, allay the Court's concerns. And any lingering concerns can be completely addressed with supplemental evidence in the TPP subclass case, and any appropriate limiting instruction as warranted, while simultaneously adhering to the law of this case (and, again, no supplementation would be required in the consumer cases because no merits expert reports have been tendered yet).

Third, courts often allow supplementation of the expert record in the same or very similar circumstances to those here. For example, in *Anthem, Inc. v. Express Scripts, Inc.*, 660 F. Supp. 3d 169, 185 (S.D.N.Y. 2023), the court allowed a TPP plaintiff to supplement the expert record where that court reached a different conclusion of law about the scope of contract damages than it had before, and after the parties had already tendered expert reports. Other courts do the same. *See, e.g.*, *Rimbert v. Eli Lilly & Co.*, 647 F.3 1247, 1256 (10th Cir. 2011) (finding abuse of discretion where successor judge did not allow submission of new expert reports after successor judge revisited predecessor judge's *Daubert* rulings); *Kewazinga Corp. v. Microsoft Corp.*, No. 18-cv-4500, 2022 WL 4236301, at *5 (S.D.N.Y. Sept. 14, 2022) (inviting argument on request to file supplemental expert reports); *Via*

Vadis, LLC v. Amazon.com, No. 14-cv-0813, 2022 WL 1667560, at *1 (W.D. Tex. May 24, 2022) (allowing expert supplementation).

Finally, if the Court determines Plaintiffs' current damages model cannot be presented to a jury, despite Huertas, Plaintiffs should be given the opportunity to cure this aspect of Dr. Conti's proffered opinions,[20] especially given that such a decision would reverse years' worth of prior rulings as discussed above. And where a defendant has created "uncertainty in providing damages," "'justice and sound public policy alike require' that the defendant 'bear the risk of the uncertainty thus produced.'" *State v. United Parcel Serv.*, 253 F. Supp. 3d 583, 687 (S.D.N.Y. 2017) (quoting *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 565 (1931)).

As opposed to this practical approach, consistent with the case law designed to avoid prejudice where issues can be addressed in a reasonable manner, Defendants press the ill-founded suggestion discussed above that this Court throw out *all* of the prior rulings, and order new extensive briefing on motions to dismiss, class certification, and summary judgment. That is simply untenable, manifestly unjust, prejudicial, and inconsistent with this Circuit's case law. *See supra* Parts I & III.

[20] Again, the Court previously indicated it was inclined to allow Dr. Conti to presume worthlessness, and in all events to opine on the damages amounts, which calculations are not disputed by the defense.

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In sum, years' worth of the Parties' and the judiciary's resources have been invested into bringing all of these economic loss claims to the doorstep of trial, twice. The economic loss side of this MDL represents a significant share of the potential defense exposure. Since the inception of this MDL more than five years ago, the immensely over-arching question has been, and remains: What were these unbargained-for contaminated VCDs worth? *See, e.g.*, July 28, 2022 CMC Tr. at 22-23 ("But I still think the question we need to have answered or seem to need to have answered is whether or not this stuff was contaminated and whether it was worth anything, you know, to the purchasers or anyone else who paid for it.").

This is why Judge Kugler opted to try an economic loss subclass trial first.[21] Plaintiffs say the contaminated pills were worth nothing; Defendants say they were worth exactly what was paid, or some amount in excess of zero. The parties, the Court, and Special Master Vanaskie have already expended substantial time and expense to ready the economic loss subclass trial against Defendants ZHP, Teva, and Torrent. Instead of throwing out all of that prior work and effort and going back to square one, as Defendants suggest (in essence, imposing the litigation "redo" this

[21] At the time, Plaintiffs requested that a consumer subclass trial proceed first. ECF 392.

Court rejected in July), the more prudent course is to allow supplementation of the expert record in the TPP subclass trial case against ZHP, Teva, and Torrent, and to schedule a consumer subclass trial case against ZHP, Teva, and Torrent on a parallel track to the personal injury bellwether cases now being worked up for trial.

One final point related to *Huertas*. There, the Third Circuit found that evidence of whether anyone actually got cancer from their use of Bayer's benzene-contaminated products is irrelevant in the context of an economic loss trial:

> Although Bayer's recall notice explained "the levels detected are not expected to cause adverse health consequences," App. 136, the economic injury addressed here is not for costs associated with adverse health consequences.

Huertas, at *16 & n.14. In other words, evidence relating to general causation is not relevant in the context of these class economic loss claims. It is the risk that matters in this context, not actual causation of cancer.

V. There is No Basis to Revisit the General Causation Rulings

The same principles discussed *supra* counsel against the wholesale reopening of the general causation expert discovery phase. The parties already tendered general causation expert reports; Rule 702 motions were filed as to all experts; and all of those motions were adjudicated in conjunction with hearings or the submission of expert declarations consistent with Third Circuit law. *See, e.g.*, *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999) ("[a]n in limine hearing will obviously

not be required whenever a *Daubert* objection is raised to a proffer of expert evidence. Whether to hold one rests in the sound discretion of the district court."); *see also Oddi v. Ford Motor Co.*, 234 F.3d 136, 154 (3d Cir. 2000) (hearing especially not necessary where court "already ha[s] before it the depositions and affidavits of the [proposed] experts.").

Moreover, the December 2023 amendments to Rule 702 did not change the evidentiary standards for expert evidence. *See* Fed. R. Evid. 702, adv. comm. notes (Dec. 2023). Defendants do not cite a single case holding otherwise. Nor do Defendants cite any specific finding by Judge Kugler about the general causation experts which might not accord with Rule 702 as amended. Absent such specificity, Defendants' nebulous desire to revisit already-decided general causation rulings is unwarranted, and will result in unnecessary and prejudicial expense and delay, and distraction.

VI. There is No Need for a "Science Day"

Some courts schedule a "science day" early in a litigation for the parties to set the landscape of some of the pertinent facts and scientific underpinnings that will be developed during discovery. This litigation, however, is six years old; an enormous amount of fact discovery already has been completed; and nearly two dozen expert reports have been tendered and subject to Rule 702 briefing and rulings. The Court

has also presided over Daubert hearings. A science day will divert the parties' time and resources when they should be focusing on preparing for trial.

Respectfully,

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Cc: Counsel of record (via ECF)